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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)
03495.0320-01000

I hereby certify that this correspondence is being addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on _____

Signature _____

Typed or printed name _____

Application Number	Filed
10/802,796	March 18, 2004

First Named Inventor
Stewart COLE

Art Unit	Examiner
1654	Julie HA

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.

☑ attorney or agent of record.
Registration number 53,283.

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

Matovcik
Signature

Lisa M. Matovcik
Typed or printed name

202.408.4033
Telephone number

April 15, 2008
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

☒ Applicants now file a two-month extension of time extending the period response to the outstanding Office Action to April 18, 2008. A two-month Extension of Time Fee of $460.00 is enclosed.

☒ A Notice of Appeal Fee of $510.00 is enclosed.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: April 15, 2008

By: _____

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PATENT
Customer No. 22,852
Attorney Docket No. 03495.0320-01000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
Stewart COLE, Roland BUCHREISER-BROSCH, Stephen GORDON, and Alain BILLAULT	)	Group Art Unit: 1654
Application No.: 10/802,796	)	Examiner: Julie HA
Filed: March 18, 2004	)	
For: A METHOD FOR ISOLATING A POLYNUCLEOTIDE OF INTEREST FROM THE GENOME OF MYCOBACTERIUM USING A BAC-BASED DNA LIBRARY, APPLICATION TO THE DETECTION OF MYCOBACTERIA	)	Confirmation No.: 6307

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Applicant now replies to the Advisory Action mailed March 17, 2008, the four-month period for response beginning with the date of the Final Office Action having been extended to April 17, 2008, by a request for one month extension of time filed February 19, 2008, a request for an extension of two months, and the fee payment filed concurrently herewith. Please reconsider the above-identified application, for the reasons of record, summarized herein.

Claims 51-54 and 57 remain pending and are directed to a purified polypeptide encoded by defined regions of SEQ ID NO:1. They stand rejected, under 35 U.S.C.

§101, for lack of utility, entirely on the basis of the Office's allegation that the specification does not disclose polypeptides with GDP-D-mannose dehydratase activity, because the claimed polypeptides share only 51% homology with known GDP-D-mannose dehydratases. (Final Office Action of October 17, 2007, at pp. 3-4.)

Applicant has, however, traversed the rejection on different grounds, which have not been considered by the Office on their merits. The Office acknowledges that the "Applicant argues since the polypeptide is expressed by *M. tuberculosis* but not *M. bovis* BCG, one of skill in the art would have understood that the polypeptide of the invention would have utility to distinguish *M. bovis* BCG from *M. tuberculosis*." (*Id.*, at p. 3) Nowhere in the record, however, does the Office substantively address this argument.

Applicant first traversed the rejection in the Reply to the First Office Action. "[R]egardless of the function of the encoded polypeptide . . . the claimed polynucleotide sequence of the invention had utility simply as a consequence of its expression by *M. tuberculosis*, but not *M. bovis* BCG. (Reply to Office Action of March 12, 2007, at p. 4.) The Office upheld the rejection in its Final Action, without acknowledging that the utility of distinguishing the two bacterial strains does not relate to the enzymatic dehydratase activity of the claimed polypeptide, nor to its homology to known dehydratases.

Applicant again traversed, providing additional support for its position. The claimed polypeptides can be used in diagnostic immunoassays to distinguish a subject infected with *M. tuberculosis* from a subject vaccinated against *M. tuberculosis* with an *M. bovis* vaccine. (Reply to Final Office Action of February 19, 2008, at p. 2.) The

presence of absence of a particular genomic region can identify the presence or absence of *M. tuberculosis or M. bovis*. This ability to distinguish between these two *Mycobacterium* strains is a substantial and well-established utility. (*Id.*, at pp. 2-3.)

It is understood in the art that a diagnostic, which can distinguish between the two strains could, for example, permit more discriminating treatment of latent infections in patients immunized with *M. bovis*. Also, the drug resistance profiles of *Mycobacterium* strains are known to differ, thus a specific diagnostic can inform the choice of pharmacologic treatment.

The asserted utility is well-supported by the original specification. The claimed isolated polypeptides are encoded by the polynucleotide designated SEQ ID NO:1, with a size of about 12.7 kb, and comprising an open reading frame ("ORF6"). (Substitute Specification, filed March 18, 2004, at ¶63, ¶66, and ¶92.) This region encodes one or more polypeptides and is present in the genome of *M. tuberculosis* but not *M. bovis*. (*Id.*, at ¶63, ¶66 and ¶257.) The claimed polypeptides, encoded by this region, can be used in diagnostic immunoassays to distinguish a subject infected with *M. tuberculosis* from one vaccinated with *M. bovis*. (*Id.*, at ¶72 and ¶257.) In view of this disclosure, it is immediately apparent to those familiar with this area of biology that the claimed polypeptides have a substantial and well-established utility.

The Advisory Action of March 17, 2008, maintains the rejections of claims 51-54 and 57, "[f]or the reasons set forth in the previous [O]ffice [A]ction." (Advisory Action of March 17, 2008, at p. 2.) The record reflects that an assertion of a lack of homology with a known protein provides the rationale for these rejections. It also reflects that

Applicant's arguments stating that the claimed polypeptides are useful because they can identify a tuberculosis infection have not been addressed.

Claims 51-54 and 57 also stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the enablement requirement because the invention is not supported by a substantial utility. (Final Office Action of October 17, 2007, at pp. 4-5) A rejection for lack of utility, under 35 U.S.C. § 112, first paragraph, is improper unless the 35 U.S.C. § 101 rejection is proper. (Reply to Final Office Action of February 19, 2008, at p. 3.)

In view of the foregoing remarks, Applicant requests the Office's reconsideration and reexamination of the application, and the timely allowance of the pending claims. Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: April 15, 2008

By: _____

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